Practitioner's Docket No. 1030.004 **PAT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Snyder et al. Group No. 1611
Application No.: 10/821,745 Examiner: Ghali, Isis
Filed: April 9, 2004 Conf. 1863
For: SUSTAINED RELEASE SURGICAL DEVICE AND METHOD OF MAKING AND USING THE SAME

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Following a Final Office Action dated November 7, 2008, Applicants submit the present Request for Formal Review, by a panel of Examiners, of the legal and factual basis of the rejections pending in the present case, in accordance with the Pre-Appeal Brief Conference Pilot Program[1]. Applicants believe that the issues presented are well posed for appeal, and request formal review prior to appeal on the following grounds:

BACKGROUND SYNOPSIS OF SUBJECT MATTER

The present claimed application relates to a glaucoma shunt device that is implanted in an eye and aids the eye in reaching a desired intraocular pressure, while also providing an erodable sustained release medium that assists in treatment. The erosion helps to dynamically achieve the desired ocular pressure.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

The Office Action rejected claims 11 and 21-24 of the present invention under 35 U.S.C. § 112 as failing to comply with the written description requirement. Specifically the Office Action cites two passages as failing to have support in the specification as filed.

The first passage listed states, "flow passage between a first end located in a first portion of an eye and a second end located in a second portion of the eye." This passage has support in several locations of the specification as filed. Paragraph 0038 states, "inserted into an eye, such that the leading end of the member is located in the anterior chamber of the eye, in the pars plana portion of the eye or both." Further support comes from paragraph 0019 which states, "FIG. 1 is a top view of an eye having a cornea A, showing an implant device here inserted into a sub-conjunctival space B." When looking at Figures 1, 2, and 3 in conjunction with reading this passage it can be seen that a first end (16) is located in the cornea A (or other part of the eye as explained in paragraph 0038) and a second end is located in a sub-conjunctival space B (or other portion of the eye as illustrated by figures 1, 2, and 3).

The second passage states, "other mass under consideration." Support for this passage can be found in paragraph 0056 which states, "the local concentration of markers that are detected near the site of interest can be correlated with the reduction of the size of the wound site or **other mass under consideration**." (emphasis added)

Applicants have presented support in the originally filed specification and respectfully requests that the rejections of the claims be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

a) Incorrect Fact Findings and Lack of Evidence

Applicants believe the rejections are based upon insufficient fact finding. The facts as set forth below show that a rejection using these references cannot be maintained. The claimed invention performs two functions and neither of these functions are adequately addressed by the Office Action. First, the shunt provides a dynamic flow path to accommodate a fluid flow to relieve ocular pressure and this flow path is created by a passive device without the addition of pressure to create a flow path. Second, the shunt acts as a sustained medication delivery device—not a one time delivery of medication.

As set forth in MPEP 2143.01 THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE. On the present facts, the modifications to Stegmann (U.S. Patent No. 5,360,399) suggested by the Examiner would render the resulting structure unsuitable for its intended purpose. The Examiner has failed to

[1] Official Gazette of the United States Patent and Trademark Office, vol. 1296, Number 2, (July 12, 2005).

show how the Stegman apparatus can be modified to achieve the claimed result without eliminating the critical element taught in Stegmann—the hydraulic expansion and traumatic opening of the upstream tissue of the Schlemm's canal. If Stegmann was to eliminate the hydraulic expansion it would cease to normalize the intraocular pressure; moreover, Stegmann does not teach having the device itself pierce the upstream tissue of the Schlemm's canal. The only portion of the eye that the apparatus enters, as taught by Stegmann, is the Schlemm's canal; therefore, the apparatus itself does not facilitate reduction of intraocular pressure by allowing the fluids to flow through the glaucoma shunt to a different area of the eye. (The Stegmann application does not expressly state if the device is removed from the eye after surgery; however, there are left and right tubes that are used during the surgery, and the tubes are used one at a time so it appears, arguendo, that the tubes are removed once the opening of the upstream tissue has been completed. (See column 4, lines 47-53) If, at least one tube and likely both tubes, of the Stegmann apparatus, must be removed from the eye, to complete the surgery, then the modification of leaving the tube in the eye will result in half of the surgery suggested in Stegmann and the procedure as taught will be rendered unsatisfactory.) Therefore, Stegmann will no longer function as taught and will be rendered unsatisfactory for its intended purpose. See *In re Ratti,* 270 F.2d 810, 123 USPQ 349 (CCPA 1959). See also *In re Fritch* (CA FC 1992) 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992)("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification").

The Office Action also fails to make any findings that there was any motivation to modify Stegmann. For instance, the apparatus taught in Stegmann is not a drainage tube. It has not been shown how Stegmann uses the tube to facilitate drainage of fluids through the tube, let alone to achieve a dynamic flow path as claimed. Stegmann facilitates drainage by using the tube to create hydraulic pressure in the eye and traumatically open the upstream tissue. The application **does not** use pressure is to create a flow path. Moreover, Stegmann does not teach leaving the tube in the eye to release sustained materials. Stegmann teaches using the viscous gel one time. This gel is only used to traumatically produce openings—not for ongoing treatment after the operation. The Office Action ignores this requirement under *KSR*, and has not met its burden to establish a prima facie obviousness.

b) Improper Application of *KSR*

Applicant believes that the Office Action did not set forth an appropriate analysis to satisfy the Supreme Court's requirements from *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007). The Office has the burden to explicitly analyze:

> . . . interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")....

Applicant believes the rejections of Claims 23 and 24 are mere conclusory statements absent any "articulated reasoning with some rational underpinning to support the legal conclusions of obviousness." The Office Action fails to point out with any particularity where any reference teaches layers of sustained release material or a diminishing layer, which exposes openings allowing additional sustained release material to escape. The Office Action further fails to state where any of the references teach an implantable device that has a first end in a first portion of an eye and a second end located in a second portion of the eye. Therefore, a proper rejection under *KSR* was not made.

CONCLUSIONS

The Stegmann reference does not disclose a dynamic flow path to accommodate fluid flow for relief of ocular pressure without the addition of pressure to create a flow path, and Stegmann does not teach a shunt acting as a sustained medication delivery device. Thus, it is respectfully submitted that a prima facie case of obviousness cannot be properly made or sustained based upon the reference relied upon by the Examiner. Applicants, therefore, submit that claims 11 and 21-24 are patentable over Stegmann. Allowance of claims 11 and 21-24 is respectfully requested.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

Dated: Jan 6, ~~2008~~ 2009

Daniel P. Aleksynas
Registration No. 62,551
DOBRUSIN & THENNISCH PC
29 W. Lawrence Street
Suite 210
Pontiac, MI 48342
(248) 292-2920

Customer No. 25215